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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

[UNDER SEAL]	:	CIVIL ACTION NO.
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Plaintiff	:	FILED UNDER SEAL
	:	
v.	:	
[UNDER SEAL]	:	09
	:	
Defendants	:	

FILED
JAN 30
MICHAEL, Clerk
By Dep. Clerk

FALSE CLAIMS ACT COMPLAINT

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA; THE STATES OF CALIFORNIA, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MASSACHUSETTS; MICHIGAN, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WISCONSIN, AND THE DISTRICT OF COLUMBIA, EX REL. HERBERT J. NEVYAS, M.D.AND ANITA NEVYAS-WALLACE, M.D.	:	Civil Action No.
Plaintiffs,	:	
v.	:	
ALLERGAN, INC. AND INSPIRE PHARMACEUTICALS, INC.	:	
Defendants	:	

FILED UNDER SEAL

JURY TRIAL DEMANDED

Qui tam plaintiffs/relators Herbert J. Nevyas, M.D. and Anita Nevyas -Wallace, M.D. through their attorneys Pietragallo Gordon Alfano Bosick & Raspanti, LLP, on behalf of the United States of America, the State of California, the State of Delaware, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Louisiana, the Commonwealth of Massachusetts, the State of Michigan, the State of Montana, the State of Nevada, the State of New Hampshire, the State of New Jersey, the State of New Mexico, the State of New York, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the

Commonwealth of Virginia, the State of Wisconsin, and the District of Columbia (collectively "the States and the District of Columbia"), for their Complaint against defendants Allergan, Inc. and Inspire Pharmaceuticals, Inc. alleges based upon personal knowledge and relevant documents, as follows:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America, the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin, and the District of Columbia, arising from false and/or fraudulent records, statements and claims made, used and caused to be made, used or presented by defendant Allergan, Inc. ("Allergan") and defendant Inspire Pharmaceuticals, Inc. ("Inspire") and/or their agents, employees and co-conspirators in violation of the Federal Civil False Claims Act, 31 U.S.C. § 3729 et seq., as amended ("the FCA" or "the Act") and its state-law counterparts: the California False Claims Act, Cal. Govt Code § 12650 et seq.; the Delaware False Claims and Reporting Act, 6 Del. C. § 1201 et seq.; the Florida False Claims Act, Fla. Stat. Ann. § 68.081 et seq.; the Georgia State False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 et seq.; the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 et seq.; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/1-8; the Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5-1 et seq.; the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:439.1 et seq.; the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5A et seq.; the Michigan Medicaid False Claim

Act, M.C.L. §400.601 et seq.; the Montana False Claims Act, Mont. Code Ann. § 17-8-401 et seq.; the Nevada False Claims Act, Nev. Rev. Stat. Ann. § 357.010 et seq.; the New Hampshire False Claims Act, N.H. Rev. Stat. Ann. §167:61-b et seq.; the New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-1 et seq.; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 et seq.; the New York False Claims Act, N.Y. State Fin. Law § 187 et seq.; the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63 §5053.1 et seq; the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 et seq.; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 et seq.; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. § 36.001 et seq.; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 et seq.; the Wisconsin False Claims for Medical Assistance Act, 121 Wis. Stat. § 20.931; and the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. § 2-308.0 and § 2-308.14 et seq.

2. Upon information and belief, Defendants' have systematically and illegally promoted its prescription drug, Restasis for off-label indications, since approximately 2003.

3. Upon information and belief, Defendant Allergan has systematically and illegally promoted its prescription drug Acular LS, since approximately 2003.

4. As a direct result of Defendants' improper practices, federal and state health insurance programs including, but not limited to, Medicare, Medicaid, MediCal, CHAMPUS/TRICARE, CHAMPVA and the Federal Employee Health Benefits Program have been caused to pay false or fraudulent claims for reimbursement of off-label uses of

the Defendants' prescription drug that would not have been paid but for the defendants' illegal business practices.

5. The False Claims Act was originally enacted during the Civil War, and was substantially amended in 1986. Congress amended the Act to enhance the Government's ability to recover losses sustained as a result of fraud against the United Stated after finding that fraud in federal programs was pervasive and that the Act, which Congress characterized as the primary tool for combating government fraud, was in need of modernization. Congress intended that the amendments create incentives for individuals with knowledge of fraud against the government to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit legal resources to prosecuting fraud on the Government's behalf.

6. The Act provides that any person who knowingly submits, or causes the submission of a false or fraudulent claim to the U.S. Government for payment or approval is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of the damages sustained by the Government. Liability attaches when a defendant knowingly seeks payment, or causes others to seek payment, from the Government that is unwarranted.

7. The Act allows any person having information about a false or fraudulent claim against the Government to bring an action for himself and the Government, and to share in any recovery. The Act requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the Government time to conduct its own investigation and to determine whether to join the suit.

8. Based on these provisions, qui tam Plaintiffs seek through this action to recover on behalf of the United States and States that authorize similar qui tam actions, damages and civil penalties arising from Defendants' making or causing to be made false or fraudulent records, statements and/or claims in connection with its knowing off-label marketing of prescription drugs. Although Defendants did not directly submit claims for prescription drugs to federal and state health insurance programs, they knew that their illegal off-label marketing practices and illegal inducements would cause the submission of thousands of claims to these health programs for prescriptions that were not eligible for program reimbursement.

II. PARTIES

9. Plaintiffs/relators Herbert J. Nevyas, M.D. and Anita Nevyas –Wallace, M.D. are residents of Pennsylvania and citizens of the United States.

10. Dr. Herbert J. Nevyas is a board-certified ophthalmologist, licensed to practice medicine under the laws of Pennsylvania, New Jersey, and Florida.

11. Since 1964, Relator Herbert J. Nevyas, M.D. has been in private practice. Currently, he is a principal in Nevyas Eye Associates, which specializes in medical and surgical ophthalmology through offices in Bala Cynwyd, PA, Philadelphia, PA, and Marlton, NJ. Nevyas Eye Associates' Bala Cynwyd location houses the Delaware Valley Laser Surgery Institute, a fully accredited ambulatory surgery center, with two operating rooms, two minor surgery suites, and a dedicated LASIK surgery suite.

12. Dr. Herbert J. Nevyas earned a B.A. from the University of Pennsylvania (1952-55) and his medical degree from University of Pennsylvania School of Medicine (1955-59). Following his internship at Jefferson Medical College Hospital (1959-60) and

post-graduate studies at Institute of Ophthalmology of the University of London and Moorfields Eye Hospitals, London, UK (1960-61), Relator Herbert J. Nevyas, M.D. served his residency in Ophthalmology at the Hospital of the University of Pennsylvania (1961-64).

13. Dr. Nevyas served in the United States Army Reserve - Medical Corps (1962-66).

14. Relator Nevyas is a member of the Phi Beta Kappa Honor Society (1955) and the recipient of the Oliver Memorial Prize in Ophthalmology - University of Pennsylvania School of Medicine (1959).

15. Dr. Nevyas is a current and former member of many local, national, and international professional scientific societies, and he is presently a Fellow of the American Academy of Ophthalmology, a founding member of the American Society for Cataract and Refractive Surgery, a Fellow of the Society of Eye Surgeons, a member of the American Medical Association, and a member of the International Society of Refractive Surgeons.

16. Dr. Nevyas has written and lectured extensively on ophthalmic surgery.

17. Dr. Nevyas has served on the faculty of the department of ophthalmology at the University of Pennsylvania (since 1978) and the Medical College of Pennsylvania (since 1984). Former faculty appointments include: Jefferson Medical College (through Wills Eye Hospital)(1975-77); Temple University School of Medicine (through Wills Eye Hospital)(1972-1973); Hahnemann Hospital College (1965-1976); and the University of Pennsylvania School of Medicine (1961-1965). Presently, Dr. Nevyas has a teaching appointment at Drexel University College of Medicine.

18. Relator Anita Nevyas-Wallace, M.D. is a board-certified ophthalmologist, licensed to practice medicine under the laws of Pennsylvania and New Jersey.

19. Since 1988, Dr. Nevyas-Wallace has been in private practice with the Nevyas Eye Associates, specializing in medical and surgical ophthalmology at the Bala Cynwyd, PA office.

20. Relator Nevyas-Wallace, M.D. earned a B.S., from the University of Pennsylvania (1976-79) and her medical degree from the University of Pennsylvania School of Medicine (1979-83). Relator Nevyas-Wallace, M.D. served her residency in Ophthalmology at the University of Pennsylvania, Scheie Eye Institute (1984-87) and a fellowship in Anterior Segment Ophthalmic Surgery at the Medical College of Pennsylvania (1987-88).

21. Relator Nevyas-Wallace received honors as a University Scholar and Benjamin Franklin Scholar at the University of Pennsylvania, and she also received the American Society of Cataract and Refractive Surgery - "Best Paper of Session" Award, (1997).

22. Dr. Nevyas-Wallace is a member of many local, national, and international professional scientific societies, including the American Society of Cataract and Refractive Surgery, the International Society of Refractive Surgery, the American College of Eye Surgeons, the Pennsylvania Academy of Ophthalmology, the Outpatient Ophthalmic Surgery Society, Surgical Eye Expeditions International, and Women in Ophthalmology.

23. Relator Nevyas-Wallace has lectured extensively on refractive and cataract surgery.

24. Defendant Allergan, Inc. ("Allergan") is an international biopharmaceutical company, incorporated under the laws of the state of Delaware, and headquartered at 2525 Dupont Drive, Irvine, CA 92612. Its primary business activity in the United States relates to discovering, developing, and commercializing specialty pharmaceutical, medical device, and over-the-counter products for the ophthalmic, neurological, medical dermatological, breast aesthetics, obesity intervention, urological and other specialty markets, including the drugs at issue in this lawsuit: Restasis, and Acular LS.

25. Defendant Inspire Pharmaceuticals, Inc. ("Inspire") is an international biopharmaceutical company, incorporated under the laws of the state of Delaware, and headquartered at 4222 Emperor Boulevard, Durham, North Carolina 27703-8466. Its primary business activity in the United States relates to the development, manufacture and/or sale of pharmaceutical drugs for ophthalmic and respiratory/allergy diseases, including the drug at issue in this lawsuit: Restasis.

26. Defendants Allergan and Inspire market Restasis in the United States through co-promotion licensing, development, and marketing agreements executed between the defendants in June 2001 and amended in December 2003 and December 2008.

III. JURISDICTION AND VENUE

27. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, 28 U.S. C. § 1367 and 31 U.S.C. § 3732, the last of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3720. Under 31 U.S.C. § 3730(e), there has been no statutorily relevant

public disclosure of the "allegations or transactions" in this Complaint. Relators, moreover, would qualify under that section of False Claims Act as an "original source" of the allegations in this Complaint even had such a public disclosure occurred.

28. The Court has subject matter jurisdiction over Defendant's violations of the California False Claims Act, Cal. Govt Code § 12650 et seq.; the Delaware False Claims and Reporting Act, 6 Del. C. § 1201 et seq.; the Florida False Claims Act, Fla. Stat. Ann. § 68.081 et seq.; the Georgia State False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 et seq.; the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 et seq.; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/1-8; the Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5-1 et seq.; the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:439.1 et seq.; the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5A et seq.; the Michigan Medicaid False Claim Act, M.C.L. §400.601 et seq.; the Montana False Claims Act, Mont. Code Ann. § 17-8-401 et seq.; the Nevada False Claims Act, Nev. Rev. Stat. Ann. § 357.010 et seq.; the New Hampshire False Claims Act, N.H. Rev. Stat. Ann. §167:61-b et seq.; the New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-1 et seq.; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 et seq.; the New York False Claims Act, N.Y. State Fin. Law § 187 et seq.; the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63 §5053.1 et seq; the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 et seq.; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 et seq.; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. § 36.001 et seq.; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 et seq.; the Wisconsin False Claims for Medical Assistance Act, 121 Wis. Stat. §

20.931; and the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. § 2-308.0 and § 2-308.14 et seq., pursuant to 31 U.S.C. § 3732(b) because Defendant's violation of the State False Claims Acts and the federal FCA arise out of a common nucleus of operative fact. See also 31 U.S.C. § 3732(b) (granting district courts jurisdiction over any action brought under the laws of any state for the recovery of funds paid by a state if the action arises from the same transaction or occurrence as an action brought under the federal FCA).

29. This Court has personal jurisdiction and venue over defendants pursuant to 28 U.S.C. §§ 1391(b) and 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because the defendants have minimum contacts with the United States. Moreover, the defendants can be found in, reside and transact business in the Eastern District of Pennsylvania.

30. Venue is proper in this District pursuant to 31 U.S. C. § 3731(a) because defendants can be found in and transact business in the Eastern District of Pennsylvania. At all times relevant to this Complaint, defendants regularly conducted substantial business within the Eastern District of Pennsylvania, maintained employees and offices in Pennsylvania and made significant sales within Pennsylvania. In addition, statutory violations as alleged herein, occurred in this district.

IV. BACKGROUND

A. Restasis (Cyclosporine Ophthalmic Emulsion) 0.05%

31. Defendant Allergan's second-highest selling eye care pharmaceutical is Restasis, which is currently the only prescription drug world wide specifically for the treatment of chronic dry eye disease (keratoconjunctivitis sicca).

32. Restasis is an eye drop formulation of cyclosporine (ophthalmic emulsion 0.05%) used to treat chronic dry eye disease (Keratoconjunctivitis sicca) resulting from ocular inflammation. Chronic dry eye disease is related to inflammation of both lacrimal gland and ocular surface and frequently affects patients with autoimmune disorders. Restasis reduces inflammation in patients with chronic dry eye disease.

33. In December 2002, the Food and Drug Administration (FDA) approved Restasis for the following indication: "to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca (chronic dry eye). Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs."

34. Cyclosporine is classified as an anti-inflammatory and immune suppressant. (Micromedex, DRUGPOINT D151625).

35. According to some studies of transplant patients who receive cyclosporine systemically, there is an increased risk of developing cancer related to a suspected connection between cancer progression and the immunosuppressive properties of cyclosporine.

36. Cyclosporine is not benign, but acts as a powerful immune suppressant. Cyclosporine, therefore, should be prescribed carefully and with appreciation for the attendant impact and risks to the patient.

37. Although the exact mechanism of action is not known, cyclosporine emulsion (Restasis) is thought to act as partial immunomodulator in patients whose tear production is presumed suppressed due to ocular inflammation associated with chronic dry eye disease. Published reports about cyclosporine suggest that it acts by reducing

inflammatory cells in the conjunctiva (Arch Ophthalmol 2000;118:1489-96) and by other means, such as by increasing the number of mucin secreting goblet cells (Arch Ophthalmol 2002;120:330-7). Thus, the Restasis action seems to be to reduce inflammation. However, when patients are already taking other anti-inflammatory eyedrops, the beneficial effect of Restasis on tear production is not seen.

38. Following FDA approval in 2002, Defendant Allergan has manufactured and marketed Restasis, which became available in the United States in April 2003.

39. A substantial portion of individuals who are treated with Restasis are participants in Medicare, Medicaid, and other federal and state reimbursement programs.

40. Defendant Inspire has the right to co-promote Restasis pursuant to joint licensing, development, and marketing agreements executed between the defendants in June 2001, which the defendants amended in December 2003 and most recently in December 2008.

41. Defendant Allergan employs a global marketing team, as well as regional sales and marketing organizations.

42. As of December 2007, Defendant Allergan employed approximately 2,407 sales representatives worldwide. Of these, a substantial number of sales representatives are situated and assigned throughout the United States for the sale and marketing of Restasis and other eye care products.

43. According to Allergan's financial documents, sales of Restasis generated world wide sales of $344.5 million in 2007. This represented a 27.5% increase in Restasis sales over 2006 figures. In 2006, Restasis sales generated $ 270.2 million in sales for defendant Allergan, a 41.6% increase over 2005 figures. Strong growth in Restasis sales

from 2005 to 2007 largely fueled the sales increases in defendant Allergan's eye care pharmaceuticals products lines, which accounted for nearly $1.8 billion in net sales in 2007.

44. U.S. product sales accounted for 65.7%, 67.4%, and 67.5% of defendant Allergan's sales in 2007, 2006, and 2005, respectively.

45. Defendant Allergan's sales and marketing efforts for Restasis and other specialty eye care pharmaceuticals are targeted at eye care professionals.

46. Allergan's marketing methods related to its eye care products include direct sales calls to physicians' offices, but also include advertisements in professional journals, participation in medical meetings, direct mail and internet programs to provide scientific information to specialists, including in the ophthalmic fields. Allergan has also developed training modules and seminars to update physicians regarding evolving technology in its products.

47. As of January 31, 2008, Defendant Inspire employed approximately 250 persons full time, of these, 98 were sales representatives. These sales representatives are situated and assigned throughout the United States for the sale and marketing of Restasis and other eye care products. However, according to Defendant Inspire's financial documents, it relies primarily upon defendant Allergan to assist in the distribution or sale of Restasis and according to the co-promotion arrangement between the defendants, marketing strategy is set by Defendant Allergan.

48. According to Defendant Inspire's financial documents, its co-promotion revenues attributed to sales of Restasis, were $24.4 million in 2007, $15.5 million in 2006, and $6.5 million in 2005. The change in revenue from 2006 to 2007 of 57% was

largely attributable to increased usage and increased prescriptions as a result of selling and promotional efforts. Defendant Inspire's co-promotion revenues are based on defendant Allergan's worldwide net sales of Restasis, but less than 2% of Defendant Inspire's co-promotion Restasis revenues are from sales outside the United States.

49. Defendant Allergan's sales and marketing efforts for Restasis and other specialty eye care pharmaceuticals are targeted at pediatricians, primary care physicians, eye care professionals, and allergists.

50. Defendant Inspire's sales and marketing efforts for Restasis and other eye care pharmaceuticals are focused on select pediatricians, primary care physicians, eye care professionals and allergists.

B. Acular LS (Ketorolac Tromethamine) 0.4%

51. Defendant Allergan's leading ophthalmic anti-inflammatory is Acular (ketorolac ophthalmic solution) 0.5%. Acular is a registered trademark of and is licensed from its developer, Syntex (U.S.A.) Inc., a business unit of Hoffman-LaRoche Inc.

52. In November 1992, the Food and Drug Administration (FDA) approved Acular for the following indication: "ACULAR ophthalmic solution is indicated for the temporary relief of itching due to seasonal allergic conjunctivitis. ACULAR ophthalmic solution is also indicated for the treatment of postoperative inflammation in patients who have undergone cataract extraction."

53. Defendant Allergan's Acular PF (ketorolac ophthalmic solution) 0.5%. was the first, and currently remains the only unit-dose, preservative-free topical non-steroidal anti-inflammatory drug, or NSAID, in the United States.

54. In November 1997, the Food and Drug Administration (FDA) approved Acular PF for the following indication "ACULAR PF ophthalmic solution is indicated for the reduction of ocular pain and photophobia following incisional refractive surgery."

55. Defendant Allergan's Acular LS (ketorolac ophthalmic solution) 0.4% is a version of Acular that has been reformulated for the reduction of ocular pain, burning and stinging.

56. In May 2003, the Food and Drug Administration (FDA) approved Acular LS for the following indication: "ACULAR LS ophthalmic solution is indicated for the reduction of ocular pain and burning/stinging following corneal refractive surgery."

57. In May 2003, the Food and Drug Administration (FDA) approved Acular LS for the following Dosage and Administration: "The recommended dose of Acular LS ophthalmic solution is one drop four times a day in the operated eye as needed for pain and burning/stinging for up to 4 days following corneal refractive surgery. Ketorolac tromethamine ophthalmic solution has been safely administered in conjunction with other ophthalmic medications such as antibiotics, beta blockers, carbonic anhydrase inhibitors, cycloplegics, and mydriatics."

58. According to Defendant Allergan, the Acular franchise (Acular, Acular PF and Acular LS) was the highest selling ophthalmic NSAID in the world during the first nine months of 2007.

59. According to Allergan, Acular LS is the number one non-steroidal anti-inflammatory by U.S. ophthalmologists.

60. A substantial portion of individuals who are treated with Acular LS are participants in Medicare, Medicaid, and other federal and state reimbursement programs.

61. Defendant Allergan's sales and marketing efforts for Acular LS and other specialty eye care pharmaceuticals are targeted at eye care professionals.

62. Allergan's marketing methods related to its eye care products include direct sales calls to physicians' offices, but also include advertisements in professional journals, participation in medical meetings, direct mail and internet programs to provide scientific information to specialists, including in the ophthalmic fields. Allergan has also developed training modules and seminars to update physicians regarding evolving technology in its products.

V. APPLICABLE LAW

A. The FDA Regulatory Scheme

63. Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the Food and Drug Administration ("FDA") that the drug is safe and effective for each of its intended uses. 21 U.S. C. §§ 355(a) &(d). Approval of the drug by the FDA is the final stage of a multi-year process of study and testing.

64. The FDA does not approve a drug for treatment of sickness in general. Instead, a drug is approved for treatment of a specific condition, for which the drug has been tested in patients. The specific approved use is called the "indication" for which the drug may be prescribed. The FDA will specify particular dosages determined to be safe and effective for each indication.

65. The indication and dosages approved by the FDA are set forth in the drug's labeling, the content of which is also reviewed by the FDA. 21 U.S. C. §§ 352,

355(d). An example of the drug's labeling is the printed insert in the drug's packaging. The FDA will only approve the new drug application if the labeling conforms to the uses and dosages that the FDA has approved. 21 U.S. C. § 355(d).

66. Under the Food and Drug Administration Modernization Act of 1977 ("FDAMA"), if a manufacturer wishes to market or promote an approved drug for alternative uses - i.e., uses not listed on the approved label - the manufacturer must resubmit the drug for another series of clinical trials similar to those for the initial approval. 21 U.S. C. § 360aaa(b)&(c). Until subsequent approval of the new use has been granted, the unapproved use is considered to be "off-label." "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified in the label, or treating a different patient population (i.e., treating a child when the drug is approved to treat adults).

67. Although the FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit doctors from prescribing the drug for uses that are different than those approved by the FDA.

68. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved. Specifically, under the Food and Drug laws, (1) a manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an off-

label purpose, and (2) a manufacturer illegally "misbrands" a drug if the drug's labeling (which included all marketing and promotional materials relating to the drug) described intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331. 352.

69. An off-label use of a drug can cease to be off label only if the manufacturer submits a supplemental application and demonstrates to the satisfaction of the FDA that the product is safe and effective for the proposed new use. 21 U.S.C. § 360aaa(b)&(c).

70. In addition to prohibiting manufacturers from directly marketing and promoting a product's off-label uses, Congress and the FDA have also sought to prevent manufacturers from employing indirect methods to accomplish the same end. For example, Congress and the FDA have attempted to regulate two of the most prevalent indirect promotional strategies: (1) manufacturer dissemination of medical and scientific publications concerning the off-label uses of their products, and (2) manufacturer support for Continuing Medical Education (CME) programs that focus on off-label uses.

71. With regard to the first practice - disseminating written information - the FDAMA only permits a manufacturer to disseminate information regarding off-label usage in response to an "unsolicited request from a health care practitioner." 21 U.S. C. § 360aaa-6 (emphasis added). In any other circumstance, a manufacturer is permitted to disseminate information concerning the off-label uses of a drug only after the manufacturer has submitted an application to the FDA seeking approval of the drug for off-label use; has provided the materials to the FDA prior to dissemination; and the

materials themselves must be in an unabridged form and must not be false or misleading. 21 U.S. C. §§ 360aaa(b)&(c); 360aaa-1.

72. With regard to manufacturer involvement in CME programs, the FDA's examination of these practices led to publication of an agency enforcement policy in 1997 entitled, "Guidance for Industry: Industry-Supported Scientific and Educational Activities," 62 Fed. Reg. 64,074, 64,093, 1997 WL 740420 (F.R.)(1997). This guidance document states that CME programs must be truly independent of the drug companies, and sets forth a number of factors that the FDA will consider in determining whether a program is "free from the supporting company's influence and bias." Id. These factors include, among others, an examination of the relationship between the program provider and supporting company, the company's control of content and selection of presenters, whether there is a meaningful disclosure of the company's funding and role in the program, whether multiple presentations of the same program are held, whether the audience is selected by the sales and marketing department of the company, and whether information about the supporting company's product is disseminated after the initial program other than in response to an unsolicited request. Id. The promotion of off-label drug uses at a CME program which fails this test of "independence" violates Congress; off-label marketing restrictions.

73. In sum, the off-label regulatory scheme protects patients and consumers by insuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body, the FDA.

B. Prescription Drug Reimbursement Under Federal Health Care Programs

74. Whether a drug is FDA-approved for a particular use will largely determine whether a prescription for that use will be reimbursed under Medicaid, Medicare, and other federal and state health care programs.

1. The Medicaid Program

75. Medicaid is a public assistance program providing for payment of medical expenses for low-income patients. Funding for Medicaid is shared between the federal government and state governments. The Medicaid program subsidizes the purchase of more prescription drugs than any other program in the United States.

76. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the federal government will pay for through its funding of state Medicaid programs. Federal reimbursement for prescription drugs under the Medicaid program is limited to "covered outpatient drugs." 41 U.S. C. § 1396b(i)(10), 1396r-8(k)(2), (3). Covered outpatient drugs are drugs that are used for "a medically accepted indication." Id., § 1396r-8(k)(3).

77. A medically accepted indication, in turn, is a use which is listed in the labeling approved by the FDA, or use of which is supported by one of the drug compendia identified in the Medicaid statute. Id. § 1396r-8(k)(6). During the time period relevant to this Complaint, many of the off-label uses of drugs promoted by Defendants for Restasis and by Defendant Allergan for Acular LS were not eligible for reimbursement from Medicaid because such off-label uses were neither listed in the

labeling approved by the FDA nor otherwise supported as safe and effective by any of the drug compendia specified by the Medicaid statute.

78. Additionally, because Defendants' unlawful off-label marketing efforts were designed to generate overutilization of their drugs in situations in which the drugs either were not proven safe and effective or were not medically necessary for treatment of patients' specific medical conditions, Defendants caused physicians to submit claims for reimbursement to Medicaid that were unwarranted and therefore false.

2. Medicare Part D

79. Section 1860D-2 of the Social Security Act, 42 U.S.C. 1395w-102, provides for out-patient prescription drugs for Medicare beneficiaries, called "Medicare Part D" benefits.

80. Part D drugs do not include drugs so prescribed and dispensed or administered to an individual that payment as is available for that individual under Medicare Part A or Part B.

81. Medicare Part D benefits (prescription coverage) are available to all Medicare beneficiaries, regardless of income and resources, health status, or current prescription expenses.

82. Federal statutes and regulations restrict the drugs and drug uses that the federal government will pay for through Medicare Part D. Federal reimbursement for prescription drugs under the Medicare Part D is limited to "covered Part D drugs." Section 1860D-2 of the Social Security Act, 42 U.S.C. 1395w-102(e)(1). Covered Part D drugs are drugs that are used for "a medically accepted indication." Id. § 1395w-102(e)(1)(B).

83. Section 1860D-2 of the Social Security Act, 42 U.S.C. 1395w-102(e)(1)(B) limits the term "medically-accepted indication" by referencing Section 1927(k)(6) of the Social Security Act, a provision in the Medicaid statute. The federal government will pay for prescriptions under Medicare Part D only for medically accepted indications, which are either listed in the labeling approved by the FDA, or use of which is supported by one of the drug compendia identified in the Medicaid statute, Section 1927(g)(1)(B)(i) of the Social Security Act.

84. CMS makes payments for Medicare Part D benefits from the Medicare Prescription Drug Account.

85. During the time period relevant to this Complaint, many of the off-label uses of drugs promoted by Defendants for Restasis and by Defendant Allergan for Acular LS were not eligible for reimbursement from Medicare Part D because such off-label uses were neither listed in the labeling approved by the FDA, nor otherwise supported as safe and effective by any of the drug compendia specified by the Medicaid statute.

86. Additionally, because Defendants' unlawful off-label marketing efforts were designed to generate overutilization of their drugs in situations in which the drugs either were not proven safe and effective, or were not medically necessary for treatment of patients' specific medical conditions, Defendants caused physicians to submit claims for reimbursement to Medicare Part D that were unwarranted and therefore false.

3. Other Federal Health Care Programs

87. In addition to Medicaid and Medicare, the federal government reimburses a portion of the cost of prescription drugs under several other federal health care

programs, including but not limited to CHAMPUS/TRICARE,CHAMPVA and the Federal Employees Health Benefit Program.

88. CHAMPUS/TRICARE, administered by the United States Department of Defense, is a health care program for individuals and dependents affiliated with the armed forces. CHAMPVA, administered by the United States Department of veteran Affairs, is a health care program for the families of veterans with 100 percent service-connected disability. The Federal Employee Health Benefit Program, administered by the United States Office of Personnel Management, provides health insurance for federal employees, retirees, and survivors. Coverage of off-label drug use under these programs is similar to coverage under the Medicaid program. See e.g., TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1(b)(2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A0(2) (June 6, 2002).

89. During the time period relevant to this Complaint, the off-label uses of the Defendants' prescription Restasis promoted by Defendants did not qualify for reimbursement under any of the various federal health care programs because there was inadequate approval or support for such drugs to be eligible for reimbursement and/or because Defendants' unlawful marketing activity created overutilization of such drugs in situations where they were not medically necessary for treatment of patients' specific medical conditions.

90. During the time period relevant to this Complaint, the off-label uses of the Defendant Allergan's prescription Acular LS promoted by Defendant Allergan did not qualify for reimbursement under any of the various federal health care programs because there was inadequate approval or support for such drug to be eligible for reimbursement

and/or because Defendants' unlawful marketing activity created overutilization of such drugs in situations where they were not medically necessary for treatment of patients' specific medical conditions.

VI. ALLEGATIONS:

A. DEFENDANTS HAVE ILLEGALLY PROMOTED RESTASIS FOR OFF-LABEL USES

91. Dr. Herbert Nevyas and Dr. Anita Nevyas-Wallace are members of a robust ophthalmology, cataract, and refractive surgery practice particularly targeted by Defendant Allergan's marketing efforts.

92. Since approximately 2003, Relators have received Defendants Allergan's promotional and marketing materials for Restasis through advertisements in professional journals, participation in medical meetings, direct mail and internet programs to provide scientific information to specialists, including in the ophthalmic fields. Allergan has also developed training modules and seminars to update physicians regarding evolving technology in its products, which Relators have seen from time to time as they attend various professional conferences and/or meetings through out the United States.

93. In approximately January 2004, Defendant Inspire began promoting Restasis pursuant to the defendants' June 2001 joint license, development and marketing agreement (amended in December 2003), which provided that defendant Allergan was primarily responsible to develop and implement marketing activities for Restasis and which gave defendant Allergan final authority to make marketing decisions.

94. However, for many years prior to November 2008, neither Relator Herbert Nevyas, M.D., nor Relator Anita Nevyas-Wallace, M.D. has invited an Allergan sales representative to make a direct sales call to their physicians' offices.

1. Allergan's Representative's Meeting with Relator Nevyas on November 5, 2008

95. Shortly before November 2008, Relator Herbert J. Nevyas, M.D. received a hand-written letter from Allergan's Territory manager, Matt Schlegel, requesting the opportunity to meet with Relator Nevyas to discuss Allergan's products, including Restasis.

96. Relator Nevyas agreed to meet with Allergan representative Schlegel on November 5, 2008 at Relator Nevyas's Bala Cynwyd, Pennsylvania office.

97. Mr. Schlegel and Dr, Nevyas met in Dr. Nevyas's office on November 5, 2008 from about 4:05 p.m. until approximately 4:45 p.m.

98. During their meeting, Matt Schlegel discussed the following Allergan products: Restasis, Zymar, and Acular LS, but the vast majority of their time was devoted to Mr. Schlegel's promotional message for Restasis.

99. While in Dr. Nevyas's office, Allergan's Territory Manager recommended that Dr. Nevyas prescribe Restasis for his patients the following off-label uses:

a. Perfectly healthy patients: According to Allergan, Restasis should be used to treat every refractive surgical patient, even those with no complaints and no reason to suspect dry eye at any preoperative point. According to Allergan, these patients should be started on Restasis as a prophylactic at least one month prior to surgery in the event they should develop a dry eye condition postoperatively, and then they should continue to be prescribed Restasis for three months post-surgery;

b. Pre-Cataract Patients: According to Allergan, Restasis should be used to treat all pre-cataract patients, even those not currently experiencing dry

eye, especially where the doctor is concerned about refractive outcome, meaning those who have refractive lenses (i.e. ReZoom, ReSTOR, or Crystalens). These patients should be started on Restasis as a prophylactic at least one month prior to surgery, and then they should continue to be prescribed Restasis for three months post-surgery;

c. Any patient with dry eye: Restasis should be used to treat any patient with dry eye, without limiting its use to autoimmune dry eye or keratoconjunctivitis sicca.

100. During this same November 2008 meeting, Defendant Allergan's territory manager also provided Relator Herbert Nevyas with a folder containing his business card along with the following materials:

A. Various articles and peer-reviewed studies regarding dry-eye treatments, which were stamped with a label indicating that the articles contain information that is inconsistent or differs from the FDA-approved package insert for Restasis, including: "Dysfunctional Tear Syndrome," Behrens, Ashley, M.D., et al., CORNEA, Vol. 25, No. 8, pp. 900-907 (September 2006); and "Safety and Efficacy of Cyclosporine 0.05% Drops Versus Unpreserved Artificial Tears in Dry-Eye Patients Having Laser in Situ Keratomileusis," Salib, George, M., M.D., et al, Journal of Cataract & Refractive Surgery, Vol. 32, No. 5, pp. 772-778 (May 2006).

B. A chart entitled "Philadelphia Area Regional Coverage," purporting to compare the coverage of Restasis, Zymar, Acular, and four other

ophthalmic drugs (including three drugs manufactured by competitors of Defendant Allergan), by government and private insurers in the "Philadelphia Area"

C. A chart entitled "EyeCare Formulary Coverage Reference as of 9/10/08," purporting to compare the coverage of Restasis, Zymar, Acular and three other ophthalmic drugs (Nevanac, Xibrom and Vigamox, all manufactured by competitors of Defendant Allergan), by government and private insurers across Pennsylvania.

D. Various articles and peer-reviewed studies regarding which were stamped with a label indicating that the articles contain information, including off-label uses, not approved by the FDA for Acular LS, including: "Preoperative Ketorolac Tromethamine 0.4% in Phacoemulsification Outcomes: Parmacokinetic-Response Curve," Donnenfeld, Eric, D., M.D., et al. Journal of Cataract & Refractive Surgery, Vol. 32, No. 9. pp. 1474-1482 (September 2006); "Evaluation of 0.4% Ketorolac Tromethamine Ophthalmic Solution Versus 0.5% Ketorolac Tromethamine Ophthalmic Solution After Phacoemulsification and Intraocular Lens Implantation," Sandoval, Helga, et al., Journal of Ocular Pharmacology and Therapeutics, Vol. 22, No. 4, pp. 251-257 (November 4, 2006); Ketorolac Tromethamine LS 0.4% Versus Nepafenac 0.1% in Patients having Cataract Surgery Prospective Randomized Double-Masked Clinical Trial," Duong, Hon-

Vu, M.D., et al., Journal of Cataract & Refractive Surgery, Vol. 33, No. 11, pp. 1925-1929 (November 2007).

E. Various articles and peer-reviewed studies regarding Zymar, at least one of which was stamped with a label indicating that the article contained information, including off-label uses, not approved by the FDA for Zymar, namely "A randomized, investigator-masked clinical trial comparing the efficacy and safety of gatifloxacin 0.3% administered BID versus QID for the treatment of acute bacterial conjunctivitis," Yee, Richard, et al., Current Medical Research and Opinion, Vol. 21, No. 3, pp. 425-432 (2005).

F. A chart entitled "Zymar VS Vigamox on Price," purporting to show that Zymar, a product manufactured by Defendant Allergan, has a 40% lower cost per milliliter than Vigamox, a product manufactured by Alcon Pharmaceuticals.

101. None of the off-label uses that Defendant Allergan recommended to Dr. Nevyas, as described above in Paragraphs 99, is supported by one of the drug compendia identified in the Medicaid statute.

102. During the November 2008 meeting, Mr. Schlegel identified numerous local physicians whom he claimed used Restasis in the off-label manners being promoted by defendant Allergan.

103. During the November 2008 meeting, Dr. Nevyas and Mr. Schlegel also discussed an invitation that Dr. Nevyas had previously received from Allergan to participate in a marketing guidance program entitled "ocular Surgery and Infection:

Evaluating the Therapeutic Options." According to the invitation, which Dr. Nevyas showed to Mr. Schlegel, Allergan invited Dr. Nevyas to attend this program to be held from May 2-4, 2008, at the InterContinental Hotel in Chicago, Illinois. (Appendix 39). The invitation also promises that attendees will receive "a consulting fee of $400," a "$100 travel stipend," roundtrip airfare, hotel accommodations, and all scheduled meals. Dr. Nevyas asked Mr. Schlegel, during their November 2008 meeting, why he received this invitation since he did not use a lot of Allergan products. Mr. Schlegel replied that Allergan "automatically" sends these invitations to physicians who do not use a lot of Allergan products.

104. At the end of the meeting, Relator Nevyas informed Mr. Schlegel that he would discuss the Allergan products with other members of his practice.

2. Allergan's Marketing Representative's Meeting with Relator Nevyas-Wallace on December 19, 2008

105. After the November 5, 2008, meeting between Relator Nevyas and Allergan's territory sales manager, Relator Anita Nevyas-Wallace contacted the territory manager and agreed to meet with him to discuss Allergan's products further.

106. Relator Nevyas-Wallace agreed to meet with Allergan representative Schlegel on December 19, 2008 at Relator Nevyas-Wallace's Bala Cynwyd, Pennsylvania office.

107. Mr. Schlegel and Dr. Nevyas-Wallace met in her office from about 10:00 am until approximately 11:30 a.m. on December 19, 2008.

108. During their meeting, Matt Schlegel discussed the following Allergan pharmaceutical products: Restasis, Acular LS, and Zymar, and they also discussed

Allergan's artificial tears, Optive and Optive-S, but the vast majority of their time was devoted to Mr. Schlegel's promotional message for Restasis.

109. While in Dr. Nevyas-Wallace's office, Defendant Allergan's Territory Manager recommended that Relator Nevyas-Wallace prescribe Restasis for her patients for the following off-label uses:

a. Perfectly healthy patients: According to Allergan, Restasis should be used to treat every surgical patient receiving ICLs (Implantable Collamer Lenses), all LASIK patients, and all ocular plastic surgery patients, both functional and cosmetic, even those with no complaints and no reason to suspect dry eye at any preoperative point, should be started on Restasis as a prophylactic. Ideally this should start at least one month prior to surgery, but no less than two weeks before surgery, to prevent the development of a dry eye condition postoperatively, and then they should continue to be prescribed Restasis for three months post-surgery, or indefinitely, if necessary;

b. Pre-Cataract Patients: According to Allergan, Restasis should be used to treat all pre-surgical cataract patients, even those not currently experiencing dry eye, especially where the doctor is concerned about refractive outcome, meaning those who have refractive lenses (i.e. ReZoom, ReSTOR, or Crystalens). Ideally these patients should be started on Restasis at least one month prior to surgery, but no less than two weeks before surgery, and then they should continue to be prescribed Restasis for three months post-surgery;

c. Existing patients with dry eye: According to Allergan, Restasis should be used to treat any patient with dry eye, without limiting its use to autoimmune dry eye or keratoconjunctivitis sicca, who uses artificial tears more than twice per day;

d. New dry eye patients: According to Allergan, Restasis should be used to treat both the new patient with tired and gritty eyes and who has not yet been tried on artificial tears, and any other patient whose chart has been coded for dry eye and who has not yet been tried on artificial tears, without limiting its use to autoimmune dry eye or keratoconjunctivitis sicca.

e. All contact lens wearers: According to Allergan, every person who wears contacts should be on Restasis because the lenses and their solutions dry out the eyes.

110. During this same December 2008 meeting, Allergan's territory manager also provided Relator Anita Nevyas-Wallace with a folder containing his business card along with the following:

A. Various articles and peer-reviewed studies regarding dry-eye treatments, which were stamped with a label indicating that the articles contain information that is inconsistent or differs from the FDA-approved package insert for Restasis, including: "Agreement of Physician Treatment Practices with the International Task Force Guidelines for Diagnosis and Treatment of Dry Eye Disease," Wilson, Steven, M.D., et al., CORNEA, Vol. 26, No. 3, pp. 284-289 (April

2007); "Dysfunctional Tear Syndrome," Behrens, Ashley, M.D., et al., CORNEA, Vol. 25, No. 8, pp. 900-907 (September 2006); and "Safety and Efficacy of Cyclosporine 0.05% Drops Versus Unpreserved Artificial Tears in Dry-Eye Patients Having Laser in Situ Keratomileusis," Salib, George. M., M.D., et al, Journal of Cataract & Refractive Surgery, Vol. 32, No. 5, pp. 772-778 (May 2006); "The Impact of Topical Cyclosporine A Emulsion 0.05% on the Outcomes of Patients with Keratoconjunctivitis sicca," Stonecipher, Karl, et al., Current Medical Research and Opinions, Vol. 21, No. 7, pp. 1057-1063 (2005).

B. Various articles and peer-reviewed studies regarding which were stamped with a label indicating that the articles contain information, including off-label uses, not approved by the FDA for Acular and Acular LS, including: "Preoperative Ketorolac Tromethamine 0.4% in Phacoemulsification Outcomes: Parmacokinetic-Response Curve," Donnenfeld, Eric, D., M.D., et al. Journal of Cataract & Refractive Surgery, Vol. 32, No. 9, pp. 1474-1482 (September 2006); "Evaluation of 0.4% Ketorolac Tromethamine Ophthalmic Solution Versus 0.5% Ketorolac Tromethamine Ophthalmic Solution After Phacoemulsification and Intraocular Lens Implantation," Sandoval, Helga, et al., Journal of Ocular Pharmacology and Therapeutics, Vol. 22, No. 4, pp. 251-257 (November 4, 2006); Ketorolac Tromethamine LS 0.4% Versus Nepafenac 0.1% in Patients having Cataract Surgery

Prospective Randomized Double-Masked Clinical Trial," Duong, Hon-Vu, M.D., et al., Journal of Cataract & Refractive Surgery, Vol. 33, No. 11, pp. 1925-1929 (November 2007); "Prostaglandin E2 Inhibition and Aqueous Concentration of Ketorolac 0.4% (Acular LS) and Nepafenac 0.1% (Nevanac) in Patients Undergoing Phacoemulsification," Bucci, Frank, A., Jr., et al., American Journal of Ophthalmology, Vol. 144, No.1, pp.146-147 (July 2007); "Ketorolac versus Prednisolone verses Combination Therapy in the Treatment of Acute Pseudophakic Cystoid Macular Edema," Heier, Jeffrey, M.D., American Academy of Ophthalmology, Vol. 107, No. 11, pp. 2034-2038 (November 2000); "Prophylaxis of Aphakic Cystoid Macular Edema without Corticosteroids," Flach, Allan, M.D., American Academy of Ophthalmology, Vol. 97, No. 10, pp. 1253-1257 (October 1990).

C. Various articles and peer-reviewed studies regarding Zymar, at least one of which was stamped with a label indicating that the article contained information, including off-label uses, not approved by the FDA for Zymar, namely "A randomized, investigator-masked clinical trial comparing the efficacy and safety of gatifloxacin 0.3% administered BID versus QID for the treatment of acute bacterial conjunctivitis," Yee, Richard, et al., Current Medical Research and Opinion, Vol. 21, No. 3, pp. 425-432 (2005).

111. During this same December 2008 meeting, Allergan's territory manager also provided Relator Anita Nevyas-Wallace with samples of Allergan's products (Restasis, Optive, Optive-S, and Acular-LS), brochures on the Restasis "Smart Start Program," and a chart entitled "Formulary Status September 2008," which purports to compare the formulary status for Allergan's Lumigan, and two other ophthalmic drugs (Xalatan and Travatan) manufactured by competitors of Defendant Allergan.

112. Defendants' Restasis Smart Start Program includes a voucher of up to $25 off of a 1-month supply of Restasis. The Smart Start voucher directs pharmacists how to enter the applicable transaction with McKesson Specialty Arizona Inc., in order for the patient to receive the $25 discount off of Restasis. According to the Smart Start voucher this discount is not available to patients of Medicare, Medicaid, or any other federal or state funded benefits programs. The Restasis Smart Start Program brochure emphasizes that patients should remain on Restasis for more than six months, and even indefinitely to maintain improvements in tear production.

113. None of the off-label uses that Defendant Allergan recommended to Dr. Nevyas-Wallace, as described above in Paragraph 109, is supported by one of the drug compendia identified in the Medicaid statute.

114. At the end of the meeting, Relator Nevyas-Wallace informed Mr. Schlegel that she would review the materials he had provided and contact him with her questions. Mr. Schlegel stated that he or a colleague would drop Restasis patient information materials off at Nevyas-Wallace's office on Monday, December 22.

115. On December 22, 2008, Mr. Schlegel sent an email to Relator Nevyas-Wallace with a chart entitled "Philadelphia Area Regional Coverage," purporting to

compare the coverage of Restasis, Zymar, Acular, and four other ophthalmic drugs (including three drugs manufactured by competitors of Defendant Allergan), by government and private insurers in the "Philadelphia Area"

116. On January 4, 2009, Mr. Schlegel sent an email to Relator Nevyas-Wallace attaching an article entitled "Evaluation of Topical Cyclosporine for the Treatment of Dry Eye Disease," Perry, Henry, D., M.D., et al., Archives of Ophthalmology, Vol. 126, No. 8, pp. 1046-1050 (August 2008). In that email, Schleglel stated in part: "In fact, the Dec. 2008 Ophthalmology Management edition discusses the Dry Eye market as a whole and how this segment of patients are under evaluated and should be looked at more closely as steady generators of revenue."

117. On January 20, 2009, Mr. Schlegel sent an email to Relator Nevyas-Wallace in which he stated as follows:

> I wanted to shoot you a quick email to gauge your interest in a new type of dinner that my counterpart and I are thinking of having in the near future. We are thinking about a dry eye discussion that will be general in nature but in the end get to the point that your eye patients today are your refractive/cataract/glaucoma/AMD patients of tomorrow. I work with a very dynamic individual who will run the 2nd half of the dinner which will center on the things that most practitioners are interested in … **the bottom line/ROI**. Topics of interest can be technician training, staff training, staff management tools (job descriptions, policy and procedures, etc.), billing and coding info., financial benchmarking tools. This list just goes on-and-on in terms of what value Allergan can bring to your practice. I hope this sort of dinner would interest you and, if so, I would make sure to get you a seat at this valuable event.

118. In another email the following day, January 21, 2009, Mr. Schlegel informed Relator Nevyas-Wallace that the dinner, referred to above in Paragraph 117, would be held on March 16, 2009, at some location in the Main Line suburbs of

Philadelphia. Mr. Schlegel also invited Relator Dr. Herbert Nevyas to attend the dinner as well.

119. Upon information and belief, Defendant Allergan promotes the off-label and illegal uses of Restasis described herein to physicians across the United States.

120. Upon information and belief, pursuant to an amendment to the defendants' joint license, development and marketing agreement dated December 24, 2008, Inspire ceased co-promoting Restasis as of December 31, 2008.

121. Upon information and belief, from January 2004 through December 31, 2008, Defendant Inspire promoted the off-label and illegal uses of Restasis described herein to physicians across the United States.

B. DEFENDANT ALLERGAN HAS ILLEGALLY PROMOTED ACULAR LS FOR OFF-LABEL USES

122. Since approximately 2003, Relators have received Defendants Allergan's promotional and marketing materials for Acular LS through advertisements in professional journals, participation in medical meetings, direct mail and internet programs to provide scientific information to specialists, including in the ophthalmic fields. Allergan has also developed training modules and seminars to update physicians regarding evolving technology in its products, which Relators have seen from time to time as they attend various professional conferences and/or meetings through out the United States.

123. On November 5, 2008 from about 4:05 p.m. until approximately 4:45 p.m., Relator Hebert Nevyas met in his office with Matthew Schlegel, Defendant Allergan's Territorial Manager.

124. During their meeting, Matt Schlegel discussed Defendant Allergan's Acular LS pharmaceutical product.

125. While in Dr. Nevyas' office, Defendant Allergan's Territory Manager Schlegel recommended that Relator Nevyas prescribe Acular LS for the following off-label use: Schlegel recommended that Relator Nevyas prescribe Acular LS for his patients in the same manner that he uses the prescription drug Nevanac pre and post-operatively with cataract patients.

126. Nevanac (Nepafenac ophthalmic suspension) 0.1% is a non-steroidal anti-inflammatory prodrug manufactured by Alcon.

127. In August 2005, the FDA approved Nevanac for the following indication: "NEVANAC ophthalmic suspension is a nonsteroidal, anti-inflammatory prodrug indicated for the treatment of pain and inflammation associated with cataract surgery."

128. In August 2005, the FDA approved Nevanac for the following Dosage and Administration: "One drop of NEVANAC ophthalmic suspension should be applied to the affected eye(s) three-times-daily beginning 1 day prior to cataract surgery, continued on the day of surgery and through the first 2 weeks of the postoperative period."

129. Acular LS is not approved by the FDA for the same indications as Nevanac. For example, Acular LS is not approved by the FDA for treatment of inflammation associated with cataract surgery. Moreover, FDA approved Dosage and Administration for Acular LS is substantially different than that approved by the FDA for Nevanac.

130. By recommending to Relator Nevyas that he prescribe Acular LS for his patients in the same manner as he prescribes Nevanac is promoting an off-label and illegal use of Acular LS.

131. During this same November 2008 meeting, Defendant Allergan's territory manager also provided Relator Herbert Nevyas with a folder containing his business card along with the materials set forth above in Paragraph 100 and the following materials:

Various articles and peer-reviewed studies regarding which were stamped with a label indicating that the articles contain information, including off-label uses, not approved by the FDA for Acular LS, including: "Preoperative Ketorolac Tromethamine 0.4% in Phacoemulsification Outcomes: Parmacokinetic-Response Curve," Donnenfeld, Eric, D., M.D., et al. Journal of Cataract & Refractive Surgery, Vol. 32, No. 9, pp. 1474-1482 (September 2006); "Evaluation of 0.4% Ketorolac Tromethamine Ophthalmic Solution Versus 0.5% Ketorolac Tromethamine Ophthalmic Solution After Phacoemulsification and Intraocular Lens Implantation," Sandoval, Helga, et al., Journal of Ocular Pharmacology and Therapeutics, Vol. 22, No. 4, pp. 251-257 (November 4, 2006); Ketorolac Tromethamine LS 0.4% Versus Nepafenac 0.1% in Patients having Cataract Surgery Prospective Randomized Double-Masked Clinical Trial," Duong, Hon-Vu, M.D., et al., Journal of Cataract & Refractive Surgery, Vol. 33, No. 11, pp. 1925-1929 (November 2007).

132. None of the off-label uses of Acular LS that Defendant Allergan recommended to Dr. Nevyas, as described above in Paragraphs 125 and 131, is supported by one of the drug compendia identified in the Medicaid statute.

133. On December 19, 2008, Matthew Schlegel, Defendant Allergan's Territorial Manager, met with Relator Nevyas-Wallace met in her office in Bala Cynwyd, Pennsylvania.

134. During their meeting, Matt Schlegel discussed Defendant Allergan's Acular LS pharmaceutical product.

135. While in Dr. Nevyas' office, Defendant Allergan's Territory Manager Schlegel recommended that Relator Nevyas-Wallace prescribe Acular LS for the following off-label use: Schlegel recommended that Relator Nevyas-Wallace prescribe Acular LS for her patients for treatment of Cystoid Macular Edema (CME).

136. Cystoid Macular Edema (CME) is a painless disorder which affects the central retina or macular. When this condition is present, multiple cyst-like (cystoid) areas of fluid appear in the macula and cause retinal swelling or edema. Although the exact cause of CME is not known, CME commonly occurs after cataract surgery. Symptoms of CME can include blurred or decreased central vision due to retinal inflammation or swelling.

137. Acular LS is not approved by the FDA for the treatment of CME.

138. Schlegel told Relator Nevyas-Wallace that he could not tell her to use Acular LS for CME, but that he has doctors saying that if their mother had CME, they would certainly want her on Acular LS.

139 During this same December 2008 meeting, Defendant Allergan's Territory Manager also provided Relator Nevyas-Wallace with a folder containing his business card along with the materials set forth above in Paragraph 110 and the following materials:

Various articles and peer-reviewed studies regarding which were stamped with a label indicating that the articles contain information, including off-label uses, not approved by the FDA for Acular and Acular LS, including: "Preoperative Ketorolac Tromethamine 0.4% in Phacoemulsification Outcomes: Parmacokinetic-Response Curve," Donnenfeld, Eric, D., M.D., et al. Journal of Cataract & Refractive Surgery, Vol. 32, No. 9, pp. 1474-1482 (September 2006); "Evaluation of 0.4% Ketorolac Tromethamine Ophthalmic Solution Versus 0.5% Ketorolac Tromethamine Ophthalmic Solution After Phacoemulsification and Intraocular Lens Implantation," Sandoval, Helga, et al., Journal of Occular Pharmacology and Therapeutics, Vol. 22, No. 4, pp. 251-257 (November 4, 2006); Ketorolac Tromethamine LS 0.4% Versus Nepafenac 0.1% in Patients having Cataract Surgery Prospective Randomized Double-Masked Clinical Trial," Duong, Hon-Vu, M.D., et al., Journal of Cataract & Refractive Surgery, Vol. 33, No. 11, pp. 1925-1929 (November 2007); "Prostaglandin E2 Inhibition and Aqueous Concentration of Ketorolac 0.4% (Acular LS) and Nepafenac 0.1% (Nevanac) in Patients Undergoing Phacoemulsification," Bucci, Frank, A., Jr., et al., American Journal of Ophthalmology, Vol. 144, No.1, pp.146-147 (July 2007); "Ketorolac versus Prednisolone verses Combination Therapy in the Treatment of Acute Pseudophakic Cystoid Macular Edema," Heier, Jeffrey, M.D., American Academy of Ophthalmology, Vol. 107, No. 11, pp. 2034-2038 (November 2000); "Prophylaxis of Aphakic Cystoid Macular Edema without

Corticosteroids," Flach, Allan, M.D., American Academy of Ophthalmology, Vol. 97, No. 10, pp. 1253-1257 (October 1990).

140. None of the off-label uses of Acular LS that Defendant Allergan recommended to Dr. Nevyas-Wallace, as described above in Paragraphs 135 to 139, is supported by one of the drug compendia identified in the Medicaid statute.

141. Upon information and belief, Defendant Allergan promotes the off-label and illegal uses of Acular LS described herein to physicians across the United States.

Count I
Federal False Claims Act
31 U.S. C. §§ 3729(a)(1) and (a)(2)

142. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 141 of this Complaint.

143. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S. C. § 3729, et seq., as amended.

144. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.

145. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Government to approve and pay such false and fraudulent claims.

146. Each prescription that was written as a result of the defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label or illegally induced

prescriptions submitted to a federal health insurance program represents a false or fraudulent claim for payment.

147. Relators cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, across the United States, and over many years. Relators have no control over, or dealings with, such entities and have no access to the records in their possession.

148. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by defendant, paid and continues to pay the claims that would not be paid but for Defendants illegal off-label marketing practices and illegal inducements.

149. By reason of the defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Federal health insurance programs have paid many thousands of claims, amounting to many hundreds of millions of dollars, for off-label prescriptions for indications that were not approved by the FDA and/or for prescriptions that were illegally induced by Defendants.

Count II
California Federal False Claims Act
Cal Govt Code § 12651(a)(1) and (2)

150. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 149 of this Complaint.

151. This is a claim for treble damages and penalties under the California False Claims Act.

152. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

153. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or uses false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

154. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continued to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

155. By reason of the Defendants' acts, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

156. The State of California is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count III
Delaware False Claims and Reporting Act
6 Del C. § 1201(a)(1) and (2)

157. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 156 of this Complaint.

158. This is a claim for treble damages and penalties under the Delaware False Claims and Reporting Act.

159. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

160. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or uses false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

161. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continued to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

162. By reason of the Defendants' acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

163. The State of Delaware is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count IV
Florida False Claims Act
Fla. Stat. Ann. § 68.082(2)

164. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 163 of this Complaint.

165. This is a claim for treble damages and penalties under the Florida False Claims Act.

166. By virtue to the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

167. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the Florida State Government to approve and pay such false and fraudulent claims.

168. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

169. By reason of the defendants; acts, the State of Florida has been damaged, and continued to be damaged, in substantial amount to be determined at trial.

170. The State of Florida is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to b e made, used or presented by Defendants.

Count V
Georgia State False Medicaid Claims Act
Ga. Code Ann. § 49-4-168.1 (a)(1) and (2)

171. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 170 of this Complaint.

172. This is a claim for treble damages and penalties under the Georgia False Claims Act.

173. By virtue to the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.

174. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the Georgia State Government to approve and pay such false and fraudulent claims.

175. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

176. By reason of the defendants; acts, the State of Georgia has been damaged, and continued to be damaged, in substantial amount to be determined at trial.

177. The State of Georgia is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to b e made, used or presented by Defendants.

Count VI
Hawaii False Claims Act
Haw. Rev. Stat. § 661-21(a)(1) and (2)

178. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 177 of this Complaint.

179. This is a claim for treble damages and penalties under the Hawaii False Claims Act.

180. By virtue to the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

181. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

182. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

183. By reason of the defendants; acts, the State of Hawaii has been damaged, and continued to be damaged, in substantial amount to be determined at trial.

184. The State of Hawaii is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to b e made, used or presented by Defendants.

Count VII
Illinois Whistleblower Reward and Protection Act
740 Ill. Comp. Stat. § 175/3(a)(1) and (2)

185. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 184 of this Complaint.

186. This is a claim for treble damages and penalties under the Illinois Whistleblower Reward and Protection Act.

187. By virtue to the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

188. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the Illinois State Government to approve and pay such false and fraudulent claims.

189. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

190. By reason of the defendants; acts, the State of Illinois has been damaged, and continued to be damaged, in substantial amount to be determined at trial.

191. The State of Illinois is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count VIII
Indiana False Claims and Whistleblower Protection Act
IC 5-11-5.5-2(b)(1), (2), and (8)

192. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 191 of this Complaint.

193. This is a claim for treble damages and penalties under the Indiana False Claims and Whistleblower Protection Act.

194. By virtue to the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.

195. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the Indiana State Government to approve and pay such false and fraudulent claims.

196. By virtue of the acts described above, Defendants knowingly caused or induced another person to perform an act described in IC 5-11-5.5-2(b)(1) and/or (2).

197. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

198. By reason of the defendants; acts, the State of Indiana has been damaged, and continued to be damaged, in substantial amount to be determined at trial.

199. The State of Indiana is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to b e made, used or presented by Defendants.

Count IX
Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. Ann. § 46:439.1-4, 46:440.1-4

200. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 199 of this Complaint.

201. This is a claim for treble damages and penalties under the Louisiana Medical Assistance Programs Integrity Law.

202. By virtue to the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval.

203. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the Louisiana State Government to approve and pay such false and fraudulent claims.

204. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

205. By reason of the defendants; acts, the State of Louisiana has been damaged, and continued to be damaged, in substantial amount to be determined at trial. The State of Louisiana is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to b e made, used or presented by Defendants.

Count X
Massachusetts False Claims Act
Mass. Gen. Laws ch. 12 § 5B(1) and (2)

206. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 205 of this Complaint.

207. This is a claim for treble damages and penalties under the Massachusetts False Claims Act.

208. By virtue to the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Commonwealth of Massachusetts for payment or approval.

209. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the Commonwealth of Massachusetts to approve and pay such false and fraudulent claims.

210. The Commonwealth of Massachusetts, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

211. By reason of the defendants; acts, the Commonwealth of Massachusetts has been damaged, and continued to be damaged, in substantial amount to be determined at trial.

212. The Commonwealth of Massachusetts is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to b e made, used or presented by Defendants.

Count XI
Michigan Medicaid False Claim Act
M.C.L. §400.603, 400.606, and 400.607

213. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 212 of this Complaint.

214. This is a claim for treble damages and penalties under the Michigan Medicaid False Claim Act.

215. By virtue to the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Michigan State Government for payment or approval.

216. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the Michigan State Government to approve and pay such false and fraudulent claims.

217. The Michigan State Government unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

218. By reason of the defendants; acts, the State of Michigan has been damaged, and continued to be damaged, in substantial amount to be determined at trial. The State of Michigan is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to b e made, used or presented by Defendants.

Count XII
Montana False Claims Act
Mont. Code Ann. § 17-8-403(1) and (2)

219. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 218 of this Complaint.

220. This is a claim for treble damages and penalties under the Montana False Claims Act.

221. By virtue to the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Montana State Government for payment or approval.

222. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the Montana State Government to approve and pay such false and fraudulent claims.

223. The Montana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

224. By reason of the defendants; acts, the State of Montana has been damaged, and continued to be damaged, in substantial amount to be determined at trial.

225. The State of Montana is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to b e made, used or presented by Defendants.

Count XIII
Nevada False Claims Act
Nev. Rev. Stat. Ann. § 357.040.1(a) and (b)

226. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 225 of this Complaint.

227. This is a claim for treble damages and penalties under the Nevada False Claims Act.

228. By virtue to the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

229. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the Nevada State Government to approve and pay such false and fraudulent claims.

230. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

231. By reason of the defendants; acts, the State of Nevada has been damaged, and continued to be damaged, in substantial amount to be determined at trial.

232. The State of Nevada is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count XIV
New Hampshire False Claims Act
N.H. Rev. Stat. Ann. §167:61-b.1(a) and (b)

233. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 232 of this Complaint.

234. This is a claim for treble damages and penalties under the New Hampshire False Claims Act.

235. By virtue to the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Hampshire State Government for payment or approval.

236. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the New Hampshire State Government to approve and pay such false and fraudulent claims.

237. The New Hampshire State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

238. By reason of the defendants; acts, the State of New Hampshire has been damaged, and continued to be damaged, in substantial amount to be determined at trial. The State of New Hampshire is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to b e made, used or presented by Defendants.

Count XV
New Jersey False Claims Act
N.J. Stat. Ann. § 2A:32C-3(a) and (b)

239. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 238 of this Complaint.

240. This is a claim for treble damages and penalties under the New Jersey False Claims Act.

241. By virtue to the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Jersey State Government for payment or approval.

242. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the New Jersey State Government to approve and pay such false and fraudulent claims.

243. The New Jersey State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

244. By reason of the defendants; acts, the State of New Jersey has been damaged, and continued to be damaged, in substantial amount to be determined at trial. The State of New Jersey is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count XVI
New Mexico Medicaid False Claims Act
N.M. Stat. Ann. § 27-14-4A and C.

245. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 244 of this Complaint.

246. This is a claim for treble damages and penalties under the New Mexico Medicaid False Claims Act.

247. By virtue to the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or approval.

248. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

249. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

250. By reason of the defendants; acts, the State of New Mexico has been damaged, and continued to be damaged, in substantial amount to be determined at trial. The State of Georgia is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to b e made, used or presented by Defendants.

Count XVII
New York False Claims Act
N.Y. State Fin. Law § 189.1(a) and (b)

251. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 250 of this Complaint.

252. This is a claim for treble damages and penalties under the New York False Claims Act.

253. By virtue to the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New York State Government for payment or approval.

254. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the New York State Government to approve and pay such false and fraudulent claims.

255. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

256. By reason of the defendants; acts, the State of New York has been damaged, and continued to be damaged, in substantial amount to be determined at trial.

257. The State of New York is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to b e made, used or presented by Defendants.

Count XVIII
Oklahoma Medicaid False Claims Act
Okla. Stat. tit. 63 §5053.11 et seq.

258. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 257 of this Complaint.

259. This is a claim for treble damages and penalties under the Oklahoma Medicaid False Claims Act.

260. By virtue to the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Oklahoma State Government for payment or approval.

261. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the Oklahoma State Government to approve and pay such false and fraudulent claims.

262. The Oklahoma State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

263. By reason of the defendants; acts, the State of Oklahoma has been damaged, and continued to be damaged, in substantial amount to be determined at trial.

264. The State of Oklahoma is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to b e made, used or presented by Defendants.

Count XIX
Rhode Island False Claims Act
R.I. Gen. Laws § 9-1.1-3(a)(1) and (2)

265. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 264 of this Complaint.

266. This is a claim for treble damages and penalties under the Rhode Island False Claims Act.

267. By virtue to the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Rhode Island State Government for payment or approval.

268. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the Rhode Island State Government to approve and pay such false and fraudulent claims.

269. The Rhode Island State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

270. By reason of the defendants; acts, the State of Rhode Island has been damaged, and continued to be damaged, in substantial amount to be determined at trial.

271. The State of Rhode Island is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to b e made, used or presented by Defendants.

Count XX
Tennessee Medicaid False Claims Act
Tenn. Code Ann. § 71-5-182(a)(1)(A) and (B)

272. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 271 of this Complaint.

273. This is a claim for treble damages and penalties under the Tennessee Medicaid False Claims Act.

274. By virtue to the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

275. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the Georgia State Government to approve and pay such false and fraudulent claims.

276. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

277. By reason of the defendants; acts, the State of Tennessee has been damaged, and continued to be damaged, in substantial amount to be determined at trial.

278. The State of Tennessee is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count XXI
Texas Medicaid Fraud Prevention Act
Tex. Hum. Res. Code Ann. § 36.002(1), (2), (4) B and (7)

279. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 278 of this Complaint.

280. This is a claim for treble damages and penalties under the Texas Medicaid Fraud Prevention Act.

281. By virtue to the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

282. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the Texas State Government to approve and pay such false and fraudulent claims.

283. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

284. By reason of the defendants; acts, the State of Texas has been damaged, and continued to be damaged, in substantial amount to be determined at trial.

285. The State of Texas is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to b e made, used or presented by Defendants.

Count XXII
Virginia Fraud Against Taxpayers Act
Va. Code Ann. § 8.01-216.3A.1 and 2

286. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 285 of this Complaint.

287. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

288. By virtue to the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Commonwealth of Virginia for payment or approval.

289. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the Commonwealth of Virginia to approve and pay such false and fraudulent claims.

290. The Commonwealth of Virginia, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

291. By reason of the defendants; acts, the Commonwealth of Virginia has been damaged, and continued to be damaged, in substantial amount to be determined at trial.

292. The Commonwealth of Virginia is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count XXIII
Wisconsin False Claims for Medical Assistance Act
121 Wis. Stat. § 20.931

293. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 292 of this Complaint.

294. This is a claim for treble damages and penalties under the Wisconsin False Claims for Medical Assistance Act.

295. By virtue to the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Wisconsin State Government for payment or approval.

296. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the Wisconsin State Government to approve and pay such false and fraudulent claims.

297. The Wisconsin State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

298. By reason of the defendants; acts, the State of Wisconsin has been damaged, and continued to be damaged, in substantial amount to be determined at trial.

299. The State of Wisconsin is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count XXIV
District of Columbia Procurement Reform Amendment Act
D.C. Code Ann. § 2-308.14 (a)(1) and (2)

300. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 299 of this Complaint.

301. This is a claim for treble damages and penalties under the District of Columbia Procurement Reform Amendment Act.

302. By virtue to the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

303. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

304. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

305. By reason of the defendants; acts, the District of Columbia has been damaged, and continued to be damaged, in substantial amount to be determined at trial. The District of Columbia is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to b e made, used or presented by Defendants.

Prayer

WHEREFORE, qui tam Plaintiffs pray for judgment against the Defendants as follows:

1. that Defendants cease and desists from violating 31 U.S. C. § 3729 et seq., and the equivalent provisions of the States and the District of Columbia's statutes as set forth above;

2. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $11,000 for each violation of 31 U.S.C. § 3729;

3. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of California has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Cal. Govt Code § 1265(a);

4. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Delaware has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of 6 Del. C. § 1201(a);

5. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Florida has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Fla. Stat. Ann. § 68.082(2);

6. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Hawaii has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Haw. Rev. Stat. § 661-21(a);

7. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Illinois has sustained because of

Defendants' actions, plus a civil penalty of $10,000 for each violation of 740 Ill. Comp. Stat. § 175/3(a);

8. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Indiana has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of IC § 5-11-5.5-2(b);

9. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Louisiana has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of La. Rev. Stat. Ann.§§ 46:439.1-4 and 46:440.1-4;

10. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the Commonwealth of Massachusetts has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Mass. Gen. L. Ch. 12 § 5B;

11. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Michigan has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of M.C.L. §§ 400.603, 400.606, and 400.607

12. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Montana has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Mont. Code Ann. § 17-8-403(1) and (2);

13. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Nevada has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Nev. Rev. Stat. Ann. § 357.040(1)(a), (b);

14. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Hampshire has sustained because of Defendants' actions, plus civil penalties for each violation of N.H. Rev. Stat. Ann. §167:61-b.1(a) and (b);

15. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Jersey has sustained because of Defendants' actions, plus civil penalties for each violation of N.J. Stat. Ann. § 2A:32C-3(a) and (b) ;

16. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Mexico has sustained because of Defendants' actions, plus civil penalties for each violation of N.M. Stat. Ann. § 27-14-4A and C [N.M. Stat. Ann. § 27-2F-4];

17. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New York has sustained because of Defendants' actions, plus civil penalties of $12,000 for each violation of N.Y. State Fin. § 189.1;

18. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Oklahoma has sustained because of

Defendants' actions, plus a civil penalty of $10,000 for each violation of Okla. Stat. tit. 63 §5053.11 et seq.

19. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Rhode Island has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of R.I. Gen. Laws § 9-1.1-3(a)(1) and (2);

20. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Tennessee has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Tenn. Code Ann. § 71-5-182(a)(1)(A) and (B);

21. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Texas has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Tex. Hum. Res. Code Ann. § 36.002(1), (2), (4) B and (7);

22. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the Commonwealth of Virginia has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Va. Code Ann. § 8.01-216.3A.1 and 2;

23. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Wisconsin has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of 121 Wis. Stat. § 20.931;

24. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the District of Columbia has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of D.C. Code Ann. § 2-308.14(a)(1)and (2);

25. that qui tam Plaintiffs be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act, and the equivalent provisions of the States and District of Columbia statutes set forth above;

26. that qui tam Plaintiffs be awarded all costs of this action, including attorneys' fees and expenses; and

27. that all Plaintiffs recover such other relief as the Court deems just and proper.

Demand for Jury Trial

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, qui tam Plaintiffs hereby demand a trial by jury.

Dated: 1-30-09

PIETRAGALLO GORDON ALFANO
BOSICK & RASPANTI, LLP

By: /s/ Marc S. Raspanti

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